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AP32573-AAA 072396.0237Serial No.  
10/075,869INFORMATION DISCLOSURE STATEMENT  
BY APPLICANTApplicant  
Robbins et al.Filing Date  
February 13, 2002Group  
TBA 1639

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## U.S. PATENT DOCUMENTS

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
PP	6 2 2 1 3 5 5	4/24/01	Dowdy	424	192.1	
	6 1 8 4 0 3 8	2/6/01	O'Hare et al.	435	455	
	6 0 1 7 7 3 5	1/25/00	O'Hare et al.	435	69.7	
	5 8 0 4 6 0 4	9/8/98	Frankel	530	324	
	5 3 3 8 6 6 5	8/16/94	Schatz	435	6	

## FOREIGN PATENT DOCUMENTS

Document No.	Date	Country	Class	SubClass	Translator Yes No
0 1 1 3 9 5 7	3/1/01	WIPO			
0 0 6 2 0 6 7	10/19/00	WIPO			
9 9 5 5 8 9 9	11/4/99	WIPO			
0 9 0 3 4 0 8	3/24/99	Europe			
9 9 1 0 4 8 5	3/4/99	WIPO			
9 9 0 6 5 4 2	2/11/99	WIPO			
9 8 5 1 8 2 5	11/19/98	WIPO			
9 8 5 1 3 2 5	11/19/98	WIPO			

## OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

PP	Mai et al. "A Proapoptotic Peptide for the Treatment of Solid Tumors", 2001, <i>Cancer Res</i> , 61:7709-7712.
	Mathis et al. "β-cell death during progression to diabetes," 2001 <i>Nature</i> 414:792.
	Mi et al., "Characterization of a Class of Cationic Peptides Able to Facilitate Efficient Protein Transduction

NY02:403374.1

Examiner

Date Considered

11/24/02

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*in Vitro and in Vivo*, 2000, *Mol Ther*, 2:339-47.

Schwarze and Dowdy, "In vivo protein transduction: intracellular delivery of biologically active proteins, compounds and DNA", 2000, *TIPS* 21: 45-48.

Elliot and O'Hare, "Cytoplasm-to-Nucleus Translocation of a Herpesvirus Tegument Protein during Cell Division", 2000, *J. Virol.* 74: 2131-2141.

Branden et al., "A peptide nucleic acid-nuclear localization signal fusion that mediates nuclear transport of DNA", 1999, *Nat. Biotechnol.* 17: 784-787.

Brown & Wouters, "A poptosis, p53, and Tumor Cell Sensitivity to Anticancer Agents", 1999, *Cancer Res* 59: 1391-1399.

Derer et al., "Direct protein transfer to terminally differentiated muscle cells", 1999, *J. Mol. Med.* 77: 609-613.

Ellerby et al., "Anti-cancer activity of targeted pro-apoptotic peptides", 1999, *Nat. Med.* 5: 1032.

Gambotto et al., "Induction of antitumor immunity by direct intratumoral injection of a recombinant adenovirus vector expressing interleukin-12", 1999, *Cancer Gene Ther.* 6: 45.

Hiroshi et al., "Interferon-alpha gene therapy in combination with CD80 transduction reduces tumorigenicity and growth of established tumor in poorly immunogenic tumor models", 1999, *Gene Ther.* 6: 1988.

Huttner et al., "Antimicrobial peptides as mediators of epithelial host defense," 1999, *Ped. Res.* 45:785.

Ivanenkov et al., "Targeted delivery of multivalent phage display vectors into mammalian cells," 1999, *Biochem. et Biophys. Acta* 1448: 463-472.

Ivanenkov et al., "Uptake and intracellular fate of phage display vectors in mammalian cells", 1999, *Biochem. et Biophys. Acta* 1448: 450-462.

Kim et al., "Adoptive-transfer therapy of tumors with the tumor-specific primary cytotoxic T cells induced in vitro with B7.1-transduced MCA205 cell line", 1999, *Cancer Immunol. Immunother.* 47: 257.

Osaki et al., "Potent antitumor effects mediated by local expression of the mature form of the interferon- $\gamma$  inducing factor, interleukin-18 (IL-18)", 1999, *Gene Ther.* 6: 808.

Pittenger et al., "Multilineage Potential of Adult Human Mesenchymal Stem Cells", 1999, *Science* 284: 143.

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P. Ponnaluri

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Nishioka et al., "Induction of Systemic and Therapeutic Antitumor Immunity Using Intratumoral Injection of Dendritic Cells Genetically Modified to Express Interleukin 12<sup>1</sup>", 1999, *Cancer Res.* 59: 4035.

Schwarze et al., "In Vivo Protein Transduction: Delivery of a Biologically Active Protein into the Mouse" 1999, *Science* 285: 1569-1572.

Vocero-Akbani et al., "Killing HIV-infected cells by transduction with an HIV protease-activated caspase 3 protein", 1999, *Nat. Med.* 5: 29-33.

Yamabe et al., "Cancer gene therapy using a pro-apoptotic gene, caspase-3", 1999, *Gene Ther.* 6: 1952-1959.

Derossi et al., "Trojan peptides: the penetratin system for intracellular delivery", 1998, *Trends in Cell Biol* 8: 84-87.

Ghivizzani et al., "Direct adenovirus-mediated gene transfer of interleukin 1 and tumor necrosis factor  $\alpha$  soluble receptors to rabbit knees with experimental arthritis has local and distal anti-arthritis effects", 1998, *Proc. Natl. Acad. Sci. USA* 95: 4613.

Mangeney and Heidmann, "Tumor cells expressing a retroviral envelope escape immune rejection *in vivo*" 1988, *Proc. Natl. Acad. Sci. USA* 95: 14920.

Nagahara et al., "Transduction of full-length TAT fusion proteins into mammalian cells: TAT-p27<sup>Kip1</sup> induces cell migration", 1998, *Nat. Med.* 4: 1449-1452.

Noffz et al., "Neutrophils but Not Eosinophils Are Involved in Growth Suppression of IL-4-Secreting Tumors<sup>1</sup>", 1988, *J. Immunol.* 160: 345.

Osaki et al., "IFN- $\gamma$ -Inducing Factor/IL-18 Administration Mediates IFN- $\gamma$ - and IL-12-Independent Antitumor Effects<sup>1</sup>", 1998, *J. Immunol.* 160: 1742.

Sakai et al., "Potential Withdrawal of Rheumatoid Synovium by the Induction of Apoptosis Using a Novel *in Vivo* Model of Rheumatoid Arthritis", 1998, *Arthritis Rheum.* 41:1251-1257.

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Villaverde et al., "A Cell Adhesion Peptide from Foot-and-Mouth Disease Virus Can Direct Cell Targeted Delivery of a Functional Enzyme", 1998, *Biotechnol. and Bioeng.* 59: 294-301.

Wakisaka et al., "Modulation by proinflammatory cytokines of Fas/Fas ligand-mediated apoptotic cell death of synovial cells in patients with rheumatoid arthritis (RA)", 1998, *Clin. Exp. Immunol.* 114: 119-128

Cayeux et al., "Influence of Gene-Modified (IL-7, IL-4, and B7) Tumor Cell Vaccines on Tumor Antigen Presentation", 1997, *J. Immunol.* 158: 2834.

Elliot and O'Hare, "Intercellular Trafficking and Protein Delivery by a Herpesvirus Structural Protein", 1997, *Cell* 188: 223-233.

Felgner, "Nonviral Strategies for Gene Therapy", 1997, *Sci. Am.* 276: 102-106.

Ghivizzani et al., "Direct retrovirus-mediated gene transfer to the synovium of the rabbit knee: implication for arthritis gene therapy", 1997, *Gene Ther.* 4: 977.

Ghivizzani et al., "Constitutive Intra-Articular Expression of Human IL-18 Following Gene Transfer to Rabbit Synovium Produces All Major Pathologies of Human Rheumatoid Arthritis", 1997, *J. Immunol.* 159: 3604.

Kato and Sugiyama, "Targeted Delivery of Peptides, Proteins, and Genes by Receptor-Mediated Endocytosis", 1997, *Crit. Rev. Ther. Drug Carrier Syst.* 14: 287-331.

Kirpotin et al., "Sterically Stabilized Anti-HER2 Immunoliposomes: Design and Targeting to Human Breast Cancer Cells *in Vitro*", 1997, *Biochemistry* 36: 66-75.

Knudsen and Nielsen, "Application of peptide nucleic acid in cancer therapy", 1997, *Anticancer Drugs* 8: 113-118.

Spragg et al., "Immunotargeting of liposomes to activated vascular endothelial cells: A strategy for site-selective delivery in the cardiovascular system", 1997, *Proc. Natl. Acad. Sci. USA* 94: 8795-8800.

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Szardenings et al., "Phage Display Selection on Whole Cells Yields a Peptide Specific for Melanocortin Receptor 1", 1997, *J. Biol. Chem.* 272: 27943-27948.

Vives et al., "A Truncated HIV-1 Tat Protein Basic Domain Rapidly Translocates through the Plasma Membrane and Accumulates in the Cell Nucleus", 1997, *J. Biol. Chem.* 272: 16010-16017.

Barry and Johnson, "Toward cell-targeting gene therapy vectors: Selection of cell-binding peptides from random peptide-presenting phage libraries", 1996, *Nat. Med.* 2: 299-305.

Berlose et al., "Conformational and associative behaviours of the third helices of antennapedia homeodomain in membrane-mimetic environments", 1996, *Eur. J. Biochem.* 242: 372.

Derossi et al., "Cell Internalization of the Third Helix of the Antennapedia Homeodomain Is Receptor-independent", 1996, *J. Biochem.* 217: 18188-18193.

Douglas et al., "Targeted gene delivery by tropism-modified adenoviral vectors", 1996, *Bio/Technology* 14:1574-1578.

Fitzgerald, "Why toxins!" 1996, *Semin. Cancer Biol.* 7: 87-95.

Moy et al., "Tat-Mediated Protein Delivery Can Facilitate MHC Class I Presentation of Antigens", 1996, *Mol. Biotechnol.* 6: 105-113.

Nita et al., "Direct Gene Delivery to Synovium", 1996, *Arthritis Rheum.* 39: 820.

Ohno et al., "Adoptive Immunotherapy with Tumor-Specific T Lymphocytes Generated from Cytokine Gene-Modified Tumor-Primed Lymph Node Cells<sup>1</sup>", 1996, *J. Immunol.* 156: 3875.

Sato et al., "Importance of receptor-mediated endocytosis in peptide delivery and targeting: kinetic aspects", 1996, *Adv. Drug Deliv. Rev.* 19: 445-467.

Shen et al., "(C) Means to Enhance Penetration: (3) Enhancement of polypeptide and protein absorption by macromolecular carriers via endocytosis and transcytosis", 1992, *Adv. Drug Deliv. Rev.* 8:93-113.

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SEP 03 2002  
PT & TRADEMARK OFFICE

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Zeigler et al., "Molecular conjugate-mediated Gene Transfer Into Isolated Human Kidneys", 1996, *Transplantation* 61: 812-817.

Wickham et al., "Targeting of adenovirus penton base to new receptors trough replacement of its RGD motif with other receptor-specific peptide motifs", 1995, *Gene Ther.* 2: 750-756.

Berns and Giraud, "Adenovirus and Adeno-Associated Virus as Vectors for Gene Therapy", 1995, *Ann. N. Y. Acad. Sci.* 772: 95-104.

Haneberg et al., "The Colon and Rectum as Inductor Sites for Local and Distant Mucosal Immunity", 1995 *Adv. Exp. Med. Biol.* 371A: 107-109.

Smith, "Viral Vectors in Gene Therapy", 1995, *Ann. Rev. Microbiol.* 49: 807-838.

Yang et al., "Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses", 1995, *J. Virol.* 69: 2004-2015.

Fawell et al., "Tat-mediated delivery of heterologous proteins into cells", 1994, *Proc. Natl. Acad. Sci. USA* 91: 664-668.

Kuzel and Rosen, "Antibodies in the treatment of human cancer", 1994, *Curr. Opin. Oncol.* 6: 622-626.

Sreerama and Woody, "Poly(Pro)II in Helices in Globular Proteins: Identification and Circular Dichroic Analysis", 1994, *Biochemistry* 33: 10022-10025.

Weitzman et al., "Adeno-associated virus (AAV) Rep proteins mediate complex formation between AAV DNA and its integration site in human DNA", 1994, *Proc. Natl. Acad. Sci. USA* 91: 5808-5812.

Kozarsky and Wilson, "Gene therapy: adenovirus vectors", 1993, *Curr. Opin. Genet. Dev.* 3: 49-50.

Miller et al., "Biology of Disease: Mucosal Immunity, HIV Transmission, and AIDS" 1993, *Lab Invest.* 68 129-145.

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Mulligan, "The Basic Science of Gene Therapy", 1993, *Science* 260: 926-932.

Vitetta et al., "Immunotoxins: magic bullets or misguided missiles?", 1993, *Immunol. Today* 14: 252-259.

Wu and Wu, "Liver-directed gene delivery", 1993, *Adv. Drug Deliv. Rev.* 12:159-167.

Zatloukal et al., "Domestic gene therapy for cancer: the utility of transferrin infection in generating 'tumor vaccines'", 1993, *Gene* 135: 199-207.

Wagner et al., "Influenza virus hemagglutinin HA-2 N-terminal fusogenic peptides augment gene transfer by transferrin-polylysine-DNA complexes: Toward a synthetic virus-like gene-transfer vehicle", 1992, *Proc. Natl. Acad. Sci.* 89: 6099-6103.

Wagner et al., "Coupling of adenovirus to transferrin-polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes", 1992, *Proc. Natl. Acad. Sci.* 89: 7934-7938.

Evans, "The Role of Proteinases in Cartilage Destruction", 1991, *Agents Actions Suppl.* 32: 135-152.

Curiel et al., "Adenovirus enhancement of transferrin-polylysine-mediated gene delivery", 1991, *Proc. Natl. Acad. Sci.* 88: 8850-8854.

Basu, "Receptor-Mediated Endocytosis of Macromolecular Conjugates in Selective Drug Delivery", 1990, *Biochem. Pharmacol.* 40: 1941-1946.

Wu and Wu, "Targeting Genes: Delivery and Persistent Expression of a Foreign Gene Driven by Mammalian Regulatory Elements *in Vivo*", 1989, *J. Biol. Chem.* 264: 16985-16987.

Frankel and Pabo, "Cellular Uptake of the Tat Protein from Human Immunodeficiency Virus", 1988, *Cell* 55: 1189-1193.

Green and Lowenstein, "Autonomous Functional Domains of Chemically Synthesized Human Immunodeficiency Virus Tat *Trans*-Activator Protein", 1988, *Cell* 55: 1179-1188.

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Wu and Wu, "Receptor-mediated Gene Delivery and Expression *in Vivo*", 1988, *J. Biol. Chem.* 263: 14621-14624.

Wu and Wu, "Receptor-mediated *in Vivo* Gene Transformation by a Soluble DNA Carrier System", 1987, *J. Biol. Chem.* 262: 4429-4432.

Bayer et al., "Preparation of Ferritin-Avidin Conjugates by Reductive Alkylation for Use in Electron Microscopic Cytochemistry", 1976, *Histochem. Cytochem.* 24: 933-939.

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